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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,919	03/31/2004	Mark C. Boomer	101896-0241	2918
21125 7590 01/10/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER COMSTOCK, DAVID C	
			ART UNIT 3733	PAPER NUMBER
			NOTIFICATION DATE 01/10/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/708,919	BOOMER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David Comstock	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-10,13-20,42,43 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-10,13-20,42,43 and 46-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 October 2007 has been entered.

### ***Drawings***

The drawings received on 31 October 2007 are accepted.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 9, 13-16, 20, 42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Yue (6,007,536).

Yue discloses a device comprising a rod 1 that can be fixed at an angle with respect to a plate 2 by means of a fastening element 4 (see Figs. 1A-1C). The device adjusts in a single plane. The plate includes a female connector having arms that receive a male connector (see Fig. 1B). A bore extends through the male and female connector components to allow rotation about a cylindrical mating element attached to the female connector. The fastening element is mated with the female connector. Both the plate and rod are capable of being implanted and used for spinal applications. Screws pass through the device and are capable of being used in the claimed manner. An end portion can function as a clamp when, for example, it is urged against an opposing portion of the device about an object.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 13-20, 42, 43, 46, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai (5,509,328).

Lai discloses a device comprising a first elongate member 10 having a female connector with opposed arms 13 and a second elongate member 20 having a male connector 40 adapted to mate to the female connector (see Fig 2). The members are adjustably coupled to one another. A fastening element locks the elongate members in

a fixed position. The devices are angularly adjustable in a single plane. The opposed arms define a recess for receiving the male connector. The device includes a bore 14 extending through the opposed arms on the female connector and through the male connector, and a central mating element 51, 52 extending through the bore for mating the male and female connectors together. The central mating element comprises a cylindrical member 51. The device rotates about this member when it is in a loosened state. The cylindrical member is fixedly coupled to a portion of the female connector, and the male connector is free to rotate about the cylindrical member when loose. The fastening element is effective to engage the cylindrical member to prevent movement of the male connector relative to the female connector when tightened. The fastening element comprises a slot 43 extending through the male connector such that the male connector is in the form of a clamp, and wherein the device further comprises a threaded fastener 44 adapted to engage and mate with the male connector to clamp the cylindrical member within the bore. The female connector and male connector rotate about a central axis extending substantially perpendicular to an axis of the first and second elongate members. The fastening element is adapted to extend into a connector along an axis that is substantially parallel to the plane of adjustability. The diameter of the first and second elongate member appears to be substantially the same. A terminal end of the second elongate member is at an angle to a longitudinal axis of the second elongate member. Although the material of the device is not specified, it would have been obvious to have formed the device from, e.g., titanium, since it has been held to be within the general skill of a worker in the art to select a known material

on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 125 USPQ 416. It is noted that titanium, among others, is a common material for devices of the type set forth by Lai for its light weight and strength and titanium is also biocompatible. Screws 35 and 36 are anchors and are capable of being secured to spinal bone (e.g. through pre-drilled holes prepared for the same).

Claims 8, 10, 47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yue (6,007,536).

With regard to claim 8, Yue discloses the claimed invention except for disclosing that the device could be comprised of rods (or plates) instead of one rod and one plate. However, given the disclosure of both a rod and a plate, it would have been obvious to a person of ordinary skill in the art, to have configured the device with two rods (or plates) instead of one rod and one plate, in order to address the exigencies of surgical necessity or patient anatomy.

With regard to claims 10, 47 and 50, Yue discloses the claimed invention except for explicitly disclosing different diameters or an offset angle of 90 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the device with differing diameters or with an offset angle of 90 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### ***Response to Arguments***

Applicant's arguments filed 31 October 2007 have been fully considered but they are not persuasive.

Lai has not been combined with non-analogous art or in any other way been combined improperly with another reference. Rather, the only modification done to the device would have been obvious and appropriate for the device, specifically, changing the material to titanium is obvious to make the device lighter and stronger. However, titanium is inherently a biocompatible material. Therefore, the issue of non-analogous art does not arise.

With regard to Yue, the mating element is engaged such that the elongate members are locked in a fixed position, e.g., as about their pivot axis and in all but one plane, relative to one another. In addition, the device of Yue comprises a clamping mechanism at its terminal end at least because the device is rigid and is capable of receiving an object to be clamped between terminal ends thereof.

Finally, Examiner maintains and repeats by reference the response to arguments mailed 04 April 2007.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo



Application/Control Number:  
10/708,919  
Art Unit: 3733

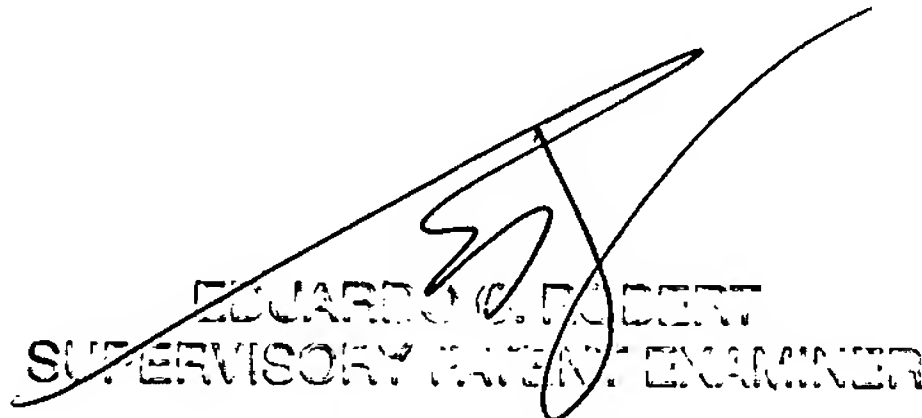
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Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock



EDUARDO G. ROBERT  
SUPERVISORY PATENT EXAMINER